

REMARKS

In view of above amendments and the following remarks, the Examiner is requested to allow Claims 1-8, 12-13, 23-26, 28-29, 46-48, 55-57, and 72-74 the only claims pending and under examination in this application, after entry of the above amendments.

Claims 1 and 48 have been amended to clarify that the wet matrix includes a plurality of ethylcellulose particles. Additionally, Claim 12 has been amended to clarify the claim language. Support for these amendments may be found throughout the specification and claims as originally filed. For instance, support may be found at paragraphs 19 and 39. Accordingly, no new matter has been added.

As no new matter has been added by way of these amendments, their entry is respectfully requested.

Claim Rejections – 35 U.S.C. § 112, first paragraph

Claim 100 has been rejected as allegedly containing new matter. The Office asserts that the claim's recitation of the phrase "substantially dissolvable," constitutes new matter. The Applicants, respectfully disagree and would like to draw the attention of the Office to paragraph 31 of the application as published, which states the following:

of at least two, three, or even four or more hours. The lozenges of the invention do not dissolve within the mouth, but rather remain intact until removed by the user and/or until a substantial fraction of the flavoring agent has been released. In the latter case, release of a substantial fraction

As can clearly be seen from the excerpt above, the disclosure specifically states that in certain embodiments the lozenge does not dissolve within the mouth. Accordingly, the Applicants assert that Claim 100 is fully supported by the specification as filed, and as such does not include new matter. Therefore, the Applicants respectfully request that this rejection be withdrawn.

Claim Rejections – 35 U.S.C. § 112, second paragraph

Claims 9 and 100 have been rejected as allegedly being indefinite. The Office asserts that the Claim's recitation of the phrase "substantially" renders the claim indefinite. However, the Applicants respectfully disagree and contend that in the context of the claims and in view of the teachings in the specification one of skill in the art would know what is meant by "substantially dissolve" and would understand the claimed lozenge does not "substantially dissolve." Therefore, according to the Court's ruling in *In re Mattison*, the phrase "substantially" is not render a claim *per se* indefinite, and in fact, is definite especially as it pertains to those instances wherein one of skill in the art would know what is meant with reference to the use of their term "substantially." *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). See also *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988). Consequently, in view of the above, the Applicants contend that Claims 9 and 100 are definite and respectfully request that this rejection be withdrawn.

Claim Rejections – 35 U.S.C. § 103(a)

Claims 1-8, 12-13, 23-25, 30, 46-48, and 72-73 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Alderman et al. (U.S. Patent No. 4,528,125).

As set forth above, an element of the rejected claims, as amended, is a lozenge that includes a sustained release wet matrix of a plurality of ethylcellulose particles and a flavoring agent. The Applicants contend that a *prima facie* case of obviousness has not been established because Alderman does not teach or suggest a lozenge that includes a sustained release wet matrix, in a first instance, nor a wet matrix that includes a plurality of ethylcellulose particles.

Rather, Alderman discloses an aqueous dispersion that includes a) cellulose ether, which is dispersed as a plurality of finely divided, individual cellulose ether particles into an aqueous phase, and b) a fragrance that is reversibly diffused from the aqueous phase and into the individual cellulose ether particles. Thus, what

Alderman is disclosing is an aqueous dispersion of fine individual cellulose particles (which individual particles are dispersed throughout a relatively large quantity of water), wherein one or more of the individual particles may include a fragrance that has diffused into the particle. This can clearly be seen with respect to column 2, lines 52-53, wherein Alderman discloses:

The cellulose ether is dispersed into the aqueous phase as a plurality of finely divided particles. While a

Hence, the cellulose particles disclosed in Alderman remain as individual particles, wherein a quantity of fragrance has diffused into the particle. For instance, see column 3, lines 17-19:

The dispersions of this invention further contain flavoring or fragrance which is reversibly diffused in the cellulose ether particles. Said flavoring or fragrance is

As such, Alderman does not disclose a matrix of a single or a plurality of particles, in the first instance, nor does Alderman disclose a wet matrix, as that term is defined by the Applicants.

The Office, however asserts that the Applicants have not defined what is meant by a "wet matrix," and therefore the Office directs the attention of the Applicants to the term matrix as that term is defined by the Merriam Webster dictionary. The Applicants, however, respectfully disagree and contend that the reliance by the Office on the Merriam Webster dictionary is neither probative nor founded, because the Applicants have in fact defined what is meant by the term "wet matrix," and according to the MPEP § 2173.05(a), it is a well-established axiom in patent law that an applicant is free to be his own lexicographer.

Specifically, at paragraph 44 of the published application, the Applicants define a "wet matrix" as:

if desired, to produce a particular flavor mix. Preferred flavoring agents are those that upon admixture with the hydrophilic polymer result in a wet matrix that, in an aqueous environment (e.g., in the mouth) gradually releases the flavoring agent and any other incorporated component. By a "wet" matrix is meant a matrix that contains a liquid phase that represents a sufficiently large fraction of the matrix to provide a discernibly wet or sticky surface, and/or a soft and rubbery consistency. Ideal flavoring agents in this

Accordingly, what is meant by "wet matrix" within the context of the present disclosure, as can clearly be seen with respect to the above definition, is that a sufficient quantity of flavoring agent has been combined with a plurality of ethylcellulose particles such that the flavoring agent, e.g., essential oil, forms a sticky glue that holds the ethylcellulose particles together the result of which is the formation of a lozenge comprising a wet matrix of a plurality of ethylcellulose particles and a flavoring agent.

Therefore, because what Alderman is disclosing is a plurality of individual cellulose particles that have diffused inside them a fragrance, Alderman does not disclose a "wet matrix," as that term is defined by the specification and employed in the claims of the present application. Consequently, because Alderman does not teach or suggest a wet matrix comprising a plurality of ethylcellulose particles and a flavoring agent, Alderman does not teach or suggest all the elements of the rejected claims, and this rejection may therefore be withdrawn.

The Applicants would additionally like to point out that the term "wet" is not being used to connote being submerged as in water. Rather, the term wet is being used in the context of surface dynamics as reflected by the term "wetting," which term refers to the relationship between the intermolecular interactions that results because of the contact between a liquid and a solid surface when the two are brought together. See, for instance, Exhibit A. In the context of the Applicants' disclosure, the term "wet" refers to the slight surface dissolution and softening that occurs when the surface of the plurality of ethylcellulose particles are contacted and enveloped by the flavoring agent, e.g., essential oil. This surface dissolution results in a single continuous phase of flavoring agent around the plurality of ethylcellulose

partices that results in the production of a sticky surface that forms a glue, which glue functions in part to hold the ethylcellulose particles together. Alderman specifically teaches against the production of a "sticky" composition. See, for instance, column 2, lines 52 to 59. Accordingly, in view of this it is clear that, contrary to the assertion by the Office, the dispersion of Alderman in and of itself cannot be considered a "wet matrix."

Further, the Applicants contend that Alderman does not teach a "matrix," as that term is used by the Applicants, because Alderman actually teaches away from a sustained release matrix system.

According to the MPEP § 2145, a prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness.

Specifically, Alderman discloses:

Another conventionally employed sustained release system comprises forming a solid matrix of a binder material such as a cellulose ether, which matrix has dispersed therein the flavoring or fragrance to be released. While such matrix systems are somewhat useful in the preparation of pharmaceutical tablets, the size of such matrix systems often precludes the use thereof in other applications. In addition, the flavoring or fragrance is often unevenly distributed in such matrix systems, causing uneven release thereof.

See column 1, lines 36 to 45.

Accordingly, the dispersions of Alderman are not sustained release solid matrix systems and because of this:

- 0 The sustained release dispersions of this invention possess several advantages over conventional sustained release systems. The flavoring or fragrance is readily diffused into the cellulose ether particles. In contrast to matrix type sustained release systems, the flavoring or
- 5 fragrance is more uniformly distributed throughout the cellulose ether particles. The physical form of the dispersion of this invention allows for a wide variety of uses not available to conventional sustained release systems. In addition, the compositions of the dispersion

See column 6, lines 30-39.

In view of the above, Alderman teaches away from the claims because Alderman discloses that dispersions are advantageous over sustained release matrix systems, such as those instantly claimed by the Applicants, because in a dispersion, as contrasted with a matrix system, the fragrance is more uniformly distributed therein and the physical form of the dispersion allows for a wide variety of uses that are not available in conventional, e.g., matrix based, sustained release systems. Accordingly, one of skill in the art would not look to Alderman for a teaching of the use of a lozenge containing a matrix of a plurality of ethylcellulose particles and a flavoring agent as a suitable dosage form as is presently claimed. Thus, for this reason alone the Applicants respectfully request that this rejection be withdrawn.

The Office, however, asserts that Alderman specifically recites "all 'matrix', 'gel matrix', or 'wet matrix' compositions." The Applicants have performed a thorough word by word review of Alderman and have not been able to find wherein Alderman recites the referenced matrix systems. The Applicants, therefore respectfully request that the Office please point out in particularity by column and line number, wherein Alderman discloses such matrix systems so that the Applicants can more fully respond to this rejection.

In view of the above, Alderman does not teach or suggest all the elements of the rejected claims. Namely, Alderman does not teach or suggest a lozenge that includes a wet matrix of a plurality of ethylcellulose particles and a flavoring agent. Alderman does not teach or suggest this because Alderman actually teaches a dispersion of separate, individual cellulose particles that have a fragrance diffused therein, and, in fact, teaches away from a matrix sustained release system, as claimed. Accordingly, a *prima facie* case of obviousness has not been established because Alderman does not teach or suggest all the elements of the rejected claims. Consequently, the Applicants respectfully request that this rejection be withdrawn.

Claims 26, 28-29, and 55-57 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Alderman in view of Ventouras (U.S. Patent No. 6,183,775).

Claims 26 and 28-29 depend from Claim 1. As set forth above, an element of Claim 1, as amended, is a lozenge that includes a sustained release wet matrix of a plurality of ethylcellulose particles and a flavoring agent. Claim 48, from which Claims 55-57 depend, includes this same element.

Accordingly, for the reasons set forth above, the Applicants contend that Alderman is deficient in that Alderman does not teach or suggest a lozenge that includes a wet matrix of a plurality of ethylcellulose particles and a flavoring agent. As Ventouras was cited solely for its disclosure of a sweetener, it fails to remedy the deficiencies of Alderman. Therefore, a *prima facie* case of obviousness has not been established because the combination of Alderman in view of Ventouras does not teach or suggest a lozenge that includes a sustained release wet matrix, in a first instance, nor a wet matrix that includes a plurality of ethylcellulose particles. For this reason alone the Applicants respectfully request that this rejection be withdrawn.

Claims 1-8, 12-13, 23-26, 28-29, 46-48, 55-57 and 72-74 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 1-7, 10-16, and 23 of copending U.S. Application No. 11/904,420.

The Applicants disagree. Nevertheless, because none of the presently pending claims of either the present application nor the copending '420 application have been allowed, the Applicants respectfully request that this rejection be held in abeyance until one or more claims of either application are found allowable, at which time an appropriate response will be advanced by the Applicant.

CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested.

It is believed that all of the pending claims have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Respectfully submitted,

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By: 

James S. Nolan
Registration No. 53,393
Attorney for Applicants
c/o MINTZ LEVIN
3580 Carmel Mountain Road,
Suite 300
San Diego, CA 92130
Tel.: 858/314-1540
Fax: 858/314-1501
Customer Number 23980

EXHIBIT A

Wetting

From Wikipedia, the free encyclopedia

Wetting is the contact between a liquid and a solid surface, resulting from intermolecular interactions when the two are brought together. The amount of wetting depends on the energies (or surface tensions) of the interfaces involved such that the total energy is minimized. The degree of wetting is described by the contact angle, the angle at which the liquid-vapor interface meets the solid-liquid interface. If the wetting is very favorable, the

contact angle will be low, and the fluid will spread to cover a larger area of the surface. If the wetting is unfavorable, the fluid will form a compact droplet on the surface. Regardless of the amount of wetting, the shape of a drop wetted to a rigid surface is roughly a truncated sphere. Various degrees of wetting are depicted in Figure 1.

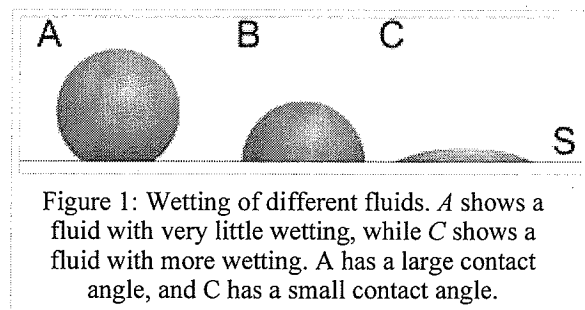


Figure 1: Wetting of different fluids. *A* shows a fluid with very little wetting, while *C* shows a fluid with more wetting. *A* has a large contact angle, and *C* has a small contact angle.

A contact angle of 90° or greater generally characterizes a surface as not-wettable, and one less than 90° as wettable. In the context of water, a wettable surface may also be termed hydrophilic and a non-wettable surface hydrophobic. Superhydrophobic surfaces have contact angles greater than 150° , showing almost no contact between the liquid drop and the surface. This is sometimes referred to as the "Lotus effect". Wetting is also important in the bonding or adherence of two materials. Wetting and the surface forces that control wetting are also responsible for other related effects, including so-called capillary effects.

Contents

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 - 1.1 Simplification to planar geometry, Young's relation
- 2 Dynamic wetting
 - 2.1 Molecular theories

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Minimization of energy, three phases

Consider the line of contact where three phases meet, as shown in Figure 2. In equilibrium, the net force per unit length acting along the boundary line between the three phases must be zero. The components of net force in the direction along each of the interfaces are given by:

$$\begin{aligned}\gamma_{\alpha\theta} + \gamma_{\theta\beta} \cos \theta + \gamma_{\alpha\beta} \cos \alpha &= 0 \\ \gamma_{\alpha\theta} \cos \theta + \gamma_{\theta\beta} + \gamma_{\alpha\beta} \cos \beta &= 0 \\ \gamma_{\alpha\theta} \cos \alpha + \gamma_{\theta\beta} \cos \beta + \gamma_{\alpha\beta} &= 0\end{aligned}$$

where α , β , and θ are the angles shown and γ_{ij} is the surface energy between the two indicated phases. These relations can also be expressed by an analog to a triangle known as Neumann's triangle, shown in Figure 3. Neumann's triangle is consistent with the geometrical restriction that $\alpha + \beta + \theta = 2\pi$, and applying the law of sines and law of cosines to it produce relations that describe how the interfacial angles depend on the ratios of surface energies. [1]

Because these three surface energies form the sides of a triangle, they are constrained by the triangle inequalities, $\gamma_{ij} < \gamma_{jk} + \gamma_{ik}$ meaning that no one of the surface tensions can exceed the sum of the other two. If three fluids with surface energies that do not follow these inequalities are brought into contact, no equilibrium configuration consistent with Figure 2 will exist.

Simplification to planar geometry, Young's relation

If the β phase is replaced by a flat rigid surface, as shown in Figure 4, then $\beta = \pi$, and the second net force equation simplifies to the Young equation, [2]

$$\gamma_{SG} = \gamma_{SL} + \gamma_{LG} \cos \theta^{[3]}$$

which relates the surface tensions between the three phases solid, liquid and gas, and which predicts the contact angle of a liquid droplet on a solid surface from knowledge of the three surface energies involved. This equation also applies if the "gas" phase is another liquid, immiscible with the droplet of the first "liquid" phase.

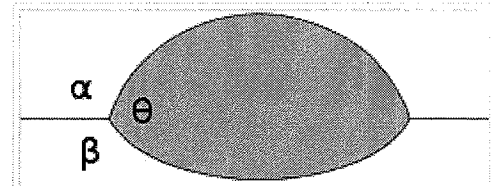


Figure 2: Coexistence of 3 fluid phases in mutual contact. α , β , and θ represent both the labels of the phases and the contact angles.

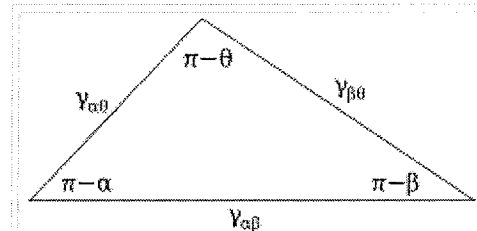


Figure 3: Neumann's triangle relating the surface energies and contact angles of 3 fluid phases coexisting in static equilibrium, as depicted in Figure 2.

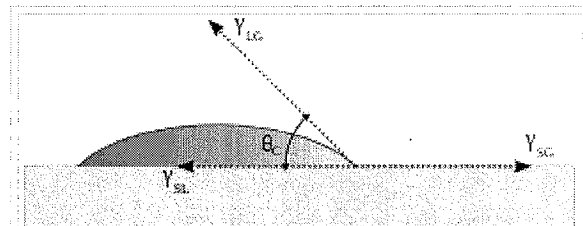


Figure 4: Contact angle of a liquid droplet wetted to a rigid solid surface.

The Young–Dupre equation dictates that neither γ_{SG} nor γ_{SL} can be larger than the sum of the other two surface energies. The consequence of this restriction is the prediction of complete wetting when $\gamma_{SG} > \gamma_{SL} + \gamma_{LG}$ and zero wetting when $\gamma_{SL} > \gamma_{SG} + \gamma_{LG}$. The lack of a solution to the Young–Dupre equation is an indicator that there is no equilibrium configuration with a contact angle between 0 and 180 degrees for those situations.

A useful parameter for gauging wetting is the *spreading parameter* S ,

$$S = \gamma_{SG} - (\gamma_{SL} + \gamma_{LG})$$

When $S > 0$, the liquid wets the surface completely (complete wetting). When $S < 0$, there is partial wetting.

Combining the spreading parameter definition with the Young relation, we obtain the Young–Dupre equation:

$$S = \gamma_{LG}(\cos \theta - 1)$$

which only has physical solutions for θ when $S < 0$.

Dynamic wetting

The above derivations all apply only to the state in which the interfaces are not moving and the phase boundary line exists in equilibrium. When a phase boundary is in motion, such as in the case of a spreading droplet or advancing contact edge, different mechanics apply. Many aspects of dynamic wetting are not fully understood, and the subject is an area of great interest to many scientists.

When a contact line such as the one in figure 4 is displaced, by either expansion or retraction of the droplet, there is a hysteresis observed in the contact angle. The static contact angle that results after expansion of a droplet is higher than that observed after a contraction. It is also often observed that the contact line does not move smoothly at the microscale. Rather, it is seen to jump abruptly in increments, by an apparent stick-slip mechanism. This has often been attributed to imperfections in the surface causing the contact line to be momentarily pinned, but this description is not complete.

When a contact line advances, covering more of the surface with liquid, the contact angle is increased and generally is related to the velocity of the contact line.^[4] A receding interface likewise has a contact angle that is reduced from the static contact angle. The limits of contact angle as velocity approaches zero in the forward and backward directions are not equal, and the range between them defines a range of contact angles that are observed as static contact angles in hysteresis experiments.

If the velocity of a contact line is increased without bound, the contact angle increases, and as it approaches 180° the gas phase will become entrained in a thin layer between the liquid and solid. This is a kinetic non-equilibrium effect which results from the contact line moving at such a high speed that complete wetting cannot occur.

Dynamic wetting is of great importance in industrial processes, where surfaces often must be coated uniformly and quickly with a liquid. Entrainment of air is unacceptable for the quality of products, but

the volume demanded necessitates coating at as high a speed as possible.^[5]

Molecular theories

Several molecular theories of dynamic wetting have been proposed. The determination of a theory that describes dynamic wetting observations is complicated by the apparent contradiction with established theories of wetting. For example, in the standard model of viscous flow, there is no slippage of the surface layer of liquid atoms along the surface, but in the immediate vicinity of a progressing contact line, it is necessary to relax this restriction to prevent the prediction of infinite shear.^[5]

When a contact line advances, it is seen to be preceded by a thin “precursor film” of submicrometer thickness, that advances ahead of the motion of the droplet. Initially, the precursor film was thought to be an artifact of volatility, but its observation in systems with no vapor presence requires a new theory. Measurements of the precursor film have been made by optical ellipsometry and also by sensitive electrical measurements. These experiments have all suffered from limitations on the liquids used and transient effects in droplet spreading, and have failed to provide any basis for a useful model of precursor film formation.^[6]

See also

- Adsorption
- Dewetting
- Sessile drop technique
- Anti-fog
- Flotation
- Electrowetting

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Categories: Fluid mechanics

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